EXHIBIT "C"

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION

No. MD-15-02641-PHX-DGC

JOHN NOTERMAN, as Personal Representative of the Estate of Pam W. Noterman,

Plaintiff,

Vs.

C.R. BARD, INC., a New Jersey Corporation, and BARD PERIPHERAL VASCULAR INC.,(a subsidiary and/or Division of Defendant C.R. BARD, INC.) an Arizona corporation

FIRST AMENDED COMPLAINT FOR DAMAGES

1.NEGLIGENCE
2.FAILURE TO WARN
3.DESIGN DEFECT
4.MANUFACTURING DEFECT
5.BREACH OF EXPRESS WARRANTY
6.BREACH OF IMPLIED WARRANTY
7.NEGLIGENT MISREPRESENTATION
8.PUNITIVE DAMAGES

DEMAND FOR JURY TRIAL

Formatted: Space After: 0 pt

~~IN THE CIRCUIT COURT OF THE TWELFTH JUDICIAL CIRCUIT~~
~~IN AND FOR SARASOTA COUNTY, FLORIDA~~
~~GENERAL JURISDICTION DIVISION~~

~~PAMELA NOTERMAN, an individual,~~

~~Plaintiff,~~

~~vs.~~

~~C.R. BARD, INC., a New Jersey Corporation, and BARD PERIPHERAL VASCULAR INC.,(a subsidiary and/or Division of Defendant C.R. BARD, INC.) an Arizona corporation~~

~~Case No.:~~

~~**COMPLAINT FOR DAMAGES**~~

~~**1. NEGLIGENCE**~~
~~**2. FAILURE TO WARN**~~
~~**3. DESIGN DEFECT**~~
~~**4. MANUFACTURING DEFECT**~~
~~**5. BREACH OF EXPRESS WARRANTY**~~
~~**6. BREACH OF IMPLIED WARRANTY**~~
~~**7. NEGLIGENT MISREPRESENTATION**~~
~~**8. PUNITIVE DAMAGES**~~

Defendants.) DEMAND FOR JURY TRIAL

PLAINTIFF'S COMPLAINT AT LAW FOR MONEY DAMAGES AND DEMAND FOR JURY TRIAL

COMES NOW Plaintiff John Noterman, as Personal Representative of the Estate of Pam W. Noterman, PAMELA NOTERMAN, by and through the undersigned counsel, and bring this complaint against Defendant, C.R. BARD, INC., and BARD PERIPHERAL VASCULAR, INC., a subsidiary corporation and/or division of C.R. BARD, INC., (collectively hereinafter "Defendants") and allege as follows:

PARTIES

1. Plaintiff-decedant Pam W. PAMELA NOTERMAN'S date of birth was is September 23, 1955. At all times relevant to this matter, Pam W. PAMELA NOTERMAN was domiciled and resided in and continues to be domiciled and reside in the city of Sarasota, the county of Sarasota, state of Florida.

2.1. Defendant, C.R. BARD INC. is a corporation organized and existing under the laws of New Jersey having its principal place of business located at 730 Central Avenue, Murray Hill, Union County, NJ, 07430 and conducts business throughout the United States including in the States of New Jersey and Florida.

3.2. Defendant, BARD PERIPHERAL VASCULAR INC., is a wholly owned subsidiary and/or division of C.R. BARD, INC., with its principal place of business at 1625 West

3rd Street, Tempe, Arizona, conducts business throughout the United States including in the State of Florida, and has conducted substantial business activity in Florida. Defendant has also carried on solicitations or service activities in the State of New Jersey and Florida.

4.3. Plaintiff-decedent believes, and therefore alleges, that each Defendant is, in some manner, legally responsible for the events and happenings set forth in this Complaint, and proximately caused injury and damages to Plaintiffs, as alleged herein.

JURISDICTION AND VENUE

5.4. Venue is proper in this Court, as Plaintiff- decedent, ~~PAMELA NOTERMAN~~Pam W. Noternan was domiciled and resided in ~~and continues to be domiciled and reside in~~ the city of Sarasota, the County of Sarasota, State of Florida.

GENERAL FACTUAL ALLEGATIONS

6.5. Plaintiff-decedent hereby incorporates by reference the averments in all paragraphs in this Complaint as though fully set forth herein. Plaintiff-decedent, on information and belief, further alleges as follows:

7.6. Plaintiff-decedent, Pam W. Noterman ~~PAMELA NOTERMAN,~~ suffered substantial injury resulting from surgical implantation with a defective and unreasonably dangerous inferior vena cava filter known as G2X Vena Cava Filter System (hereafter "G2X" or "G2X Filter"), that was designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold by Defendants beginning in 2009.

8.7. At all times relevant, Defendants misrepresented the safety of the G2X Filter, and negligently designed, manufactured, prepared, compounded, assembled, processed,

labeled, marketed, distributed, and sold the G2X Filter as safe and effective device to be surgically implanted to prevent blood clots (thrombi) from travelling from the lower portions of the body to the heart and lungs.

9.8. At all times relevant to this action, Defendants knew, and had reason to know, that the G2X Filter was not safe for the patients for whom they were prescribed and implanted, because once implanted the devices were prone to fracturing, migrating, excessively tilting, perforating the inferior vena cava wall and otherwise malfunctioning.

10.9. At all times relevant to this action, Defendants knew, and had reason to know, that patients implanted with the G2X Filter had an increased risk of suffering life threatening injuries, including but not limited to: death; hemorrhage; cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart); cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; and perforations of tissue, vessels and organs.

11.10. Despite having knowledge of the dangers presented by the G2X Filter, Defendants failed to adequately warn Plaintiff's health care providers and/or the public at large of these dangers.

INFERIOR VENA CAVA FILTERS GENERALLY

12.11. Inferior vena cava ("IVC") filters first came on to the medical market in the 1960's. Over the years, medical device manufacturers have introduced several different designs of IVC filters.

13.12. An IVC filter is a device that is designed to filter or "catch" blood clots (called "thrombi") that travel from the lower portions of the body to the heart and lungs. IVC

filters may be designed to be implanted, either permanently or temporarily, in the human body, more specifically, within the inferior vena cava.

~~14.~~13. The inferior vena cava is a vein that returns blood to the heart from the lower portions of the body. In certain people, for various reasons, thrombi travel from the vessels in the legs and pelvis, through the vena cava and into the lungs. Often times, these thrombi develop in the deep leg veins. These thrombi are called "deep vein thrombosis" or "DVT". Once thrombi reach the lungs, they are considered "pulmonary emboli" or "PE". Pulmonary emboli present risks to human health. They can, and often do, result in death.

~~15.~~14. Certain people are at increased risk for the development of DVT or PE. For instance, someone who undergoes knee or hip joint replacement surgery is at risk for developing DVT/PE. Obese patients are also at increased risk for DVT/PE. So too are people who have vascular diseases or whom have experienced previous strokes. A number of other conditions predispose people to develop DVT/PE, including "coagulopathies" and clotting disorders.

~~16.~~15. Those people at risk for DVT/PE can undergo medical treatment to manage the risk. For example, a doctor may prescribe medications like Heparin, Warfarin, or Lovenox to regulate the clotting factor of the blood. In some people who are at high risk for DVT/PE, or who cannot manage their conditions with medications, physicians may recommend surgically implanting an IVC filter to prevent thromboembolitic events.

~~17.~~16. As stated above, IVC filters have been on the market for decades. The first IVC filters marketed were permanent filters. These devices were designed to be left in a patient's IVC permanently and have long-term follow-up data (of up to 20 years and

longer) supporting their use and efficacy. Beginning in 2003, manufacturers also began marketing what are known as optional or retrievable filters. These filters are designed so that they can be surgically removed from a patient after the risk of PE has subsided. These IVC filter designs, however, were not intended to remain within the human body for indeterminate periods of time. In other words, the initial designs of retrievable IVC filters were intended to remain implanted for a finite period of time. The Recovery Filter. the G2, G2 Express, and G2x, and the G2X Filter manufactured by Defendants are examples of retrievable filters.

THE RECOVERY FILTER:FDA Clearance and Intended Use

~~18.~~17. In 2002, Defendants submitted a notification of intent to the FDA to market the "Recovery® Filter System" (hereafter "Recovery" or "Recovery Filter") for the prevention of recurrent pulmonary embolism by placement in the inferior vena cava.[1] On November 27, 2002, the FDA cleared the Recovery Filter for marketing and use in the prevention of recurrent pulmonary embolism via *permanent* placement in the vena cava in the following situations:

a. Pulmonary thromboembolism when anticoagulants are contraindicated;
b. Failure of anticoagulant therapy for thromboembolic disease;

[1] Defendants submitted the notification under Section 510(k) of the United States Food, Drug and Cosmetic Act ("Act") of 1976 (21 U.S.C. 321 *et seq*). The 510(k) review process requires any entity engaged in the design, manufacture, distribution or marketing of a device intended for human use to notify the FDA 90 days before it intends to market the device and to establish that the device is substantially equivalent to a legally marketed predicate device. (21 C.F.R. §§ 807.81, 807.92(a)(3)). Substantial equivalence means that the new device has the same intended use and technological characteristics as the predicate device. This approval process allows a manufacturer to bypass the rigorous safety scrutiny required by the pre-market approval process.

c. Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced;
d. Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

~~19.~~18. In April 2003, Defendants submitted a Section 510(k) premarket notification of intent to market the Recovery® Filter for the additional intended use of *optional retrieval*. The FDA cleared this additional intended use on July 25, 2003.

~~20.~~19. Defendants began actually marketing the device in April 2003, but did not begin full market release until 2004. Defendants were aware that the Recovery filter was also used extensively off-label, including for purely prophylactic reasons for trauma patients or patients with upcoming surgeries such as bariatric procedures.

What Is It and How Is It Used

~~21.~~20. The Recovery Filter consists of two (2) levels of six (6) radially distributed NITINOL struts that are designed to anchor the filter into the inferior vena cava and to catch any embolizing clots. There are six short struts, which are commonly referred to as the arms, and six long struts, which are commonly referred to as the legs. Each strut is held together by a single connection to a cap located at the top of the device. According to the Patent filed for this device, the short struts are primarily for "centering" or "positioning" with the vena cava, and the long struts with attached hooks are designed primarily to prevent the device from migrating in response to "normal respiratory movement" or "pulmonary embolism."

~~22.~~21. As noted above, the Recovery Filter is constructed with NITINOL, which is an acronym that stands for Nickel Titanium Naval Ordnance Laboratory. NITINOL possesses "shape memory." Meaning, NITINOL will change shape according to changes

in temperature, and then, retake its prior shape after returning to its initial temperature. When placed in saline, therefore, the NITINOL struts become soft and can be straightened to allow delivery through a small diameter catheter. The metal struts then reassume their original shape when warmed to body temperature in the vena cava.

~~23.~~22. The Recovery filter is inserted by a catheter that is guided by a physician (normally an interventional radiologist) through a blood vessel into the inferior vena cava. The Recovery Filter is designed to be retrieved in a similar fashion. The implanting physician normally reviews an imaging study prior to placement to determine size of IVC, renal vein location, and to identify any venous anomalies or clots in the vena cava. Following placement, the physician will normally use an imaging study to confirm successful placement.

Inherent Risks of the Recovery® Filter

~~24.~~23. The Recovery Filter is prone to an unreasonably high risk of failure and patient injury following placement in the human body. Multiple studies have reported Bard's Recovery Filter to have a fracture and migration rate ranging from 21% to 31.7%.[2] When such failures occur, shards of the device or the entire device can travel to the heart, where it can cause cardiac tamponade, perforation of the atrial wall, myocardial infarction and death. These fractured shards may also become too embedded in tissue or migrate to locations, such as the lungs, such that they are too dangerous to remove. These patients are exposed to a lifetime of future risk.

[2] *See e.g.,* Hull JE, Robertson SW. Bard Recovery Filter: evaluation and management of vena cava limb perforation, fracture, and migration. *J Vasc Interv Radiol.* 2009;20(1):52-60; Nicholson W, *et al.* Prevalence of Fracture and Fragment Embolization of the Bard Recovery and Bard G2 Cava Filters and Clinical Implications Including Cardiac Perforation and Tamponade. *Arch. Int. Med.* 2010 Nov.; 170:1827-31.

~~25.~~24. The Recovery Filter similarly poses a high risk of tilting and perforating the vena cava walls. When such failures occur, the device can perforate the duodenum, small bowel, ureter, which may lead to retroperitoneal hematomas, small-bowel obstructions, extended periods of severe pain, and/or death. Further, given the risks of injury in attempting to remove devices that have perforated the vena cava, the device may be irremovable. These patients are faced with a lifetime of future risk.

~~26.~~25. The Recovery Filter failures described above occur at a substantially higher rate than with other IVC filters.

~~27.~~26. Soon after the Recovery Filter's introduction to the market, Defendants began receiving large numbers of adverse event reports from health care providers.

~~28.~~27. The adverse event reports (AERs) associated with IVC filter devices demonstrates that Bard's IVC Filters are far more prone to device failure then are other similar devices. A review of the FDA MAUDE database from the years 2004-2008 reveals data to establish that Bard's IVC filters are responsible for the following percentages of all AERs:

a. 50% of all adverse events

b. 64% of all occurrences of migration of the device

c. 69% of all occurrences of vena cava wall perforation

d. 70% of all occurrences of filter fracture.

~~29.~~28. These failures are attributable, in part, to the fact that the Recovery Filter was designed so as to be unable to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

~~30.~~29. In addition to design defects, the Recovery Filter suffers from manufacturing defects. These manufacturing defects include, but are not limited to, the existence of "draw markings" and circumferential grinding markings on the exterior of the surface of the device. The presence of these draw markings and/or circumferential grinding markings further compromises the structural integrity of the device while *in vivo*. In particular, the Recovery Filter is prone to fail at or near the location of draw markings/circumferential grinding markings on the struts of the device. Put simply, the Recovery Filter is not of sufficient strength to withstand normal placement within the human body. The presence of the aforementioned exterior manufacturing defects makes the device more susceptible to failure.

What Defendants Knew of Should Have Known

~~31.~~30. Defendants knew that no clinical testing, such as animal studies or simulated use tests, was conducted to determine whether the Recovery Filter would perform safely once implanted in the human body and subjected normal *in vivo* stresses.

~~32.~~31. Soon after the Recovery Filter's introduction to the market in 2003, Defendants began receiving large numbers of adverse event reports ("AERs") from health care providers reporting that the Recovery® Filter was fracturing post-implantation and that fractured pieces and/or the entire device were migrating throughout the human body, including to the heart and lungs. Defendants also received large numbers of AERs reporting that the Recovery Filter was found to have excessively tilted and/or perforated the inferior vena cava post-implantation. These failures were often associated with reports of severe patient injuries such as:

a. Death;

b. Hemorrhage;
c. Cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart);
d. Cardiac arrhythmia and other symptoms similar to myocardial infarction;
e. Severe and persistent pain; and
f. Perforations of tissue, vessels and organs.

~~33.~~32. Within the first year of full market release of the Recovery Filter, Defendants received at least 32 AERs reporting that the Recovery Filter had fractured *in vivo* and at least 22 AERs reporting that the entire device had migrated *in vivo*. Of the 22 reported migration failures, at least nine (9) were reported to have been associated with patient death.

~~34.~~33. From 2003 through September 2005, Defendants received ever growing numbers of AERs reporting the above described failures and patient injuries. Defendants knew or should have known that the failure rates associated with the Recovery Filter were substantially higher than other similar products on the market, yet Defendants failed to warn consumers of this unreasonably dangerous device.

~~35.~~34. In late 2004 or early 2005 Defendants , without notifying consumers of the design and manufacturing flaws inherent in the Recovery Filter, began redesigning the Recovery Filter in an attempt to correct those flaws. The redesigned filter is known as the G2 Filter, which stands for second generation Recovery Filter. Bard later manufactured the G2 Express, G2x and the G2X filter, which are based on the Recovery Filter design. Once Defendants had obtained FDA approval to market the redesigned product in or around August 2005, Defendants quietly stopped marketing the Recovery Filter. Defendants failed, however, to make any effort to notify consumers of the risk inherent in the use of the Recovery Filter.

THE G2, G2 Express, and G2x FILTER SYSTEM

~~36.~~35. In 2005, Defendants redesigned its first generation retrievable filter, Recovery Filter, in an attempt to fix its design and manufacturing flaws. The redesigned filter is known as the G2 Filter, which stands for second generation Recovery Filter.

~~37.~~36. On August 10, 2005, Defendants submitted a Section 510(k) premarket notification of intent to market the G2 Filter for the prevention of recurrent pulmonary embolism via permanent placement in the inferior vena cava. Defendants cited the Recovery Filter as the substantially equivalent predicate device. Defendants stated that the differences between the Recovery Filter and the G2 Filter were primarily dimensional and no material changes or additional components were added. On August 29, 2005, the FDA cleared the G2 Filter for the same intended uses as the Recovery Filter, except that it was not cleared for retrievable use.[3]

~~38.~~37. Even after the redesigned G2 Filter was cleared for use, Defendants failed to take any steps to recall the Recovery Filter and/or to notify consumers that the failure rates associated with the Recovery Filter were substantially higher than other similar products on the market.

~~39.~~38. Defendants marketed the G2 Filter as having "enhanced fracture resistance," "improved centering," and "increased migration resistance." Despite these claims, however, Defendants failed to ensure that the changes made to the G2 Filter were sufficient to cure the defective and unreasonably dangerous nature of the device. Thus, the G2 Filter shares the same defects and health risks as its predicate device.

[3] The FDA did not clear the G2® Filter to be used as a retrievable filter until January 15, 2008.

~~40.~~39. The G2 Filter's design causes it to be of insufficient integrity and strength to withstand normal *in vivo* body stresses within the human body so as to resist fracturing, migrating, tilting, and/or perforating the inferior vena cava.

~~41.~~40. Also, like its predecessor, in addition to design defects, the G2 Filter suffers from manufacturing defects. These manufacturing defects include, but are not limited to, the existence of "draw markings" and circumferential grinding markings on the exterior of the surface of the device. The presence of these draw markings and/or circumferential grinding markings further compromises the structural integrity of the G2 Filter while *in vivo*. In particular, the G2 Filter is prone to fail at or near the location of draw markings/circumferential grinding markings on the struts of the device. Put simply, the G2 Filter is not of sufficient strength to withstand normal placement within the human body. The presence of the aforementioned exterior manufacturing defects makes the device more susceptible to fatigue failure.

~~42.~~41. As with the Recovery Filter, Defendants immediately began receiving large numbers of AERs reporting that the G2 Filter was, *inter alia*, fracturing, migrating, excessively tilting, and perforating the vena cava once implanted. These failures were again often associated with reports of severe patient injuries such as:

a. death;
b. hemorrhage;
c. cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart);
d. cardiac arrhythmia and other symptoms similar to myocardial infarction;
e. severe and persistent pain;
f. and perforations of tissue, vessels and organs.

~~43.~~42. Defendants represent the fracture rate of the G2 Filter to be 1.2%. Based upon a review of the data available in the public domain (including the FDA MAUDE database

statistics and the published medical literature), this representation does not accurately reflect the true incidence of device fracture for the G2 Filter.

~~44.~~43. A review of the MAUDE database from the years 2004-2008 reveals data to establish that the Defendants vena cava filters (including the G2 Filter) are responsible for the majority of all reported adverse events related to inferior vena cava filters.

~~45.~~44. The G2 Express filter was cleared by the FDA on July 30, 2008. The only significant difference between this filter and the G2 was a new snare tip which was designed in an effort to optimize retrieval. Bard launched and began marketing the G2 Express in August 2008. The G2 and the G2 Express are the same filter, from a design standpoint, and share the same defects and complications.

~~46.~~45. The G2x filter was cleared by the FDA on October 31, 2008. As with the G2 Express, the G2x had minimal design difference between it and the G2 Filter. Bard launched the G2x Filter in January 2009. The G2, G2 Express, and the G2x are the same filter, from a design standpoint, and share the same defects and complications.

DEFENDANTS 'S KNOWLEDGE OF THE RISK OF FAILURE ASSOCIATED WITH THE G2, G2 Express, and the G2x FILTER AND RESULTING DANGERS

~~47.~~46. Upon information and belief, Plaintiff alleges that as early as 2003, Defendants were aware and had knowledge of the fact that the Recovery Filter was defective and unreasonably dangerous and was causing injury and death to patients who had received it. Similarly, Defendants were aware as early as 2005 that the G2 Filter System family was defective and unreasonably dangerous and was causing injury and death to patients

who had received it. And due to the similarities in design, Bard should have known that the G2 Express and G2x were just as dangerous and defective.

48.47. Data establishes that the failure rate of the G2 Filter System, and filters within that family, was/is exceedingly higher than the rate that Defendants have in the past, and currently continue to publish to the medical community, members of the public. Further, Defendants are aware or should have been aware that the G2 Filter, the G2 Express, and the G2x have a substantially higher failure rate than other similar products on the market, yet they have failed to warn consumers of this fact.

49.48. Upon information and belief, from the time the G2 Filter System became available on the market, the Defendants Defendants embarked on an aggressive campaign of "off label marketing" concerning the G2 Filter System. This included representations made to physicians, healthcare professionals, and other members of the medical community that the G2 Filter System was safe and effective for retrievable use prior to the FDA approving the G2 Filter System for retrievable use.

50.49. Despite having knowledge as early as 2005 of the unreasonably dangerous and defective nature of the product, Defendants consciously disregarded the known risks and continued to actively market and offer for sale the G2 Filter System, the G2 Express, and the G2x.

SPECIFIC FACTUAL ALLEGATIONS RELATING TO PLAINTIFF

~~51.~~50. On or about November 5, 2009 Plaintiff-decedent, Pam W. Noterman ~~PAMELA NOTERMAN~~, underwent a surgical procedure to have an G2X Filter implanted. This procedure was performed at Naples Community Hospital in Naples, Florida.

~~52.~~51. This device was designed, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold by Defendants.

~~53.~~52. On or about February 16, 2011, Plaintiff-decedent presented to Lakewood Ranch Medical Center in Bradenton, Florida with chest pains. Plaintiff-decedent underwent diagnostic testing which revealed that she had a retained piece from her IVC Filter.

~~54.~~53. Subsequently, on March 10, 2011 the IVC Filter was removed and resheathed after multiple attempts and careful manipulation

~~55.~~54. The retained piece of the G2X Filter remains in Plaintiff's body to this day causing, among other things, anxiety, stress, anxiousness, and constant worry.

~~56.~~55. As a result of Defendants' wrongful conduct, Plaintiff-decedent, Pam W. Noterman ~~PAMELA NOTERMAN~~ is no longer able to sustain the active lifestyle that she had enjoyed prior to the time when she was treated with the G2X Filter. Plaintiff suffered and continues to suffer from physical and emotional pain, including but not limited to chest pains. Plaintiff can no longer take part in strenuous activity due to the incident.

CORPORATE/ VICARIOUS LIABILITY

~~57.~~56. At all times herein mentioned, each of the Defendants was the agent, servant, partner, aider and abettor, co-conspirator and/or joint venturer of each of the other Defendants herein and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture

and rendered substantial assistance and encouragement to the other Defendants, knowing that their collective conduct constituted a breach of duty owed to the Plaintiff.

~~58.~~57. There exists and, at all times herein mentioned, there existed a unity of interest in ownership between certain Defendants and other certain Defendants such that any individuality and separateness between the certain Defendants has ceased and these Defendants are the alter ego of the other certain Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as entities distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

~~59.~~58. At all times herein mentioned, Defendants, and each of them, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling products for use by the Plaintiff. As such, each Defendant is individually, as well as jointly and severally, liable to the Plaintiff for his damages.

~~60.~~59. At all times herein mentioned, the officers and/or directors of the Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew, or with the exercise of reasonable care and diligence should have known, of the hazards and dangerous propensities of said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by the Plaintiff-decedent.

FIRST CAUSE OF ACTION

NEGLIGENCE

(Against All Defendants)

~~61.~~60. Plaintiff-decedent re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

~~62.~~61. At all times relevant to this cause of action, the Defendants were in the business of designing, developing, setting specifications, manufacturing, marketing, selling, and distributing the G2X Filter.

~~63.~~62. The Defendants designed, manufactured, marketed, inspected, labeled, promoted, distributed and sold the G2X Filter that was implanted in Pam W. Noterman~~PAMELA NOTERMAN~~.

~~64.~~63. The Defendants had a duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the G2X Filter so as to avoid exposing others to foreseeable risks of harm.

~~65.~~64. The Defendants knew or reasonably should have known that the G2X Filter was dangerous or was likely to be dangerous when used in its intended or reasonably foreseeable manner.

~~66.~~65. At the time of manufacture and sale of the G2X Filter (2009 until present), the Defendants knew or should have known that the G2X Filter:

a. Was designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the device;

b. Was designed and manufactured so as to present a unreasonable risk of migration of the device and/or portions of the device; and/or

c. Was designed and manufactured so as to present a unreasonable risk of the device perforating the vena cava wall;

d. Was designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement.

~~67.~~66. At the time of manufacture and sale of the G2X Filter (beginning in 2009), the Defendants knew or should have known that using the G2X Filter in its intended use or in a reasonably foreseeable manner created a significant risk of a patient suffering severe health side effects, including, but not limited to: hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; perforations of tissue, vessels and organs; and other severe personal injuries and diseases, which are permanent in nature, including, but not limited to, death, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and treatment due to chronic injuries/illness proximately caused by the G2X Filter; and the continued risk of requiring additional medical and surgical procedures including general anesthesia, with attendant risk of life threatening complications.

a. 70. The Defendants knew or reasonably should have known that users of the G2X Filter would not realize the danger associated with using the device in its intended use and/or in a reasonably foreseeable manner.

~~68.~~67. The Defendants breached their to duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the G2X Filter in, among other ways, the following acts and omissions:

a. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;

b. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications or from other typical units from the same production line;

c. Failing to use reasonable care to warn or instruct Plaintiff, Plaintiff's physicians, or the general health care community about the G2X Filter's substantially dangerous condition or about facts making the product likely to be dangerous;

d. Failing to perform reasonable pre and post-market testing of the G2X Filter to determine whether or not the product was safe for its intended use;

e. Failing to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would prescribe, use, and implant the G2X Filter;

f. Advertising, marketing and recommending the use of the G2X Filter, while concealing and failing to disclose or warn of the dangers known by the Defendants to be connected with and inherent in the use of the G2X Filter;

g. Representing that the G2X Filter was safe for its intended use when in fact, the Defendants knew and should have known the product was not safe for its intended purpose;

h. Continuing manufacture and sale of the G2X Filter's with the knowledge that said product was dangerous and not reasonably safe, and failing to comply with FDA regulations and policy;

i. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the G2X Filter so as to avoid the risk of serious harm associated with the use of the G2X Filter;

j. Advertising, marketing, promoting and selling the G2X Filter for uses other than as approved and indicated in the product's label;

k. Failing to establish an adequate quality assurance program used in the manufacturing of the G2X Filter System;

l. Failing to establish and maintain and adequate post-market surveillance program.

~~69.~~68. A reasonable manufacturer, distributor, or seller under the same or similar circumstances would not have engaged in the before-mentioned acts and omissions.

~~70.~~69. As a direct and proximate result of the foregoing negligent acts and omissions by the Defendants, Plaintiff suffered serious physical injuries and economic damages in an amount to be determined at trial.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY-FAILURE TO WARN

(Against All Defendants)

~~71.~~70. Plaintiff-decedent re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein

~~72.~~71. The Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the G2X Filter, including the one implanted into Plaintiff, into the stream of commerce and in the course of same, directly advertised and marketed the device to consumers or persons responsible for consumers, and therefore had a duty to warn of the risk of harm associated with the use

of the device and to provide adequate instructions on the safe and proper use of the device.

~~73.~~72. At the time the Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the device into the stream of commerce, the device was defective and presented a substantial danger to users of the product when put to its intended and reasonably anticipated use, namely as a surgically implanted device used to prevent pulmonary embolisms. The Defendants failed to adequately warn of the device's known or reasonably scientifically knowable dangerous propensities, and further failed to adequately provide instructions on the safe and proper use of the device.

~~74.~~73. The Defendants knew or should have known at the time they manufactured, labeled, distributed and sold the G2X Filter that was implanted into Plaintiff that the G2X Filter posed a significant and higher risk than other similar devices of device failure (fracture, migration, tilting, and perforation of the vena cava wall) and resulting serious injuries.

~~75.~~74. The Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the G2X Filter (hereinafter "the device"); no health care provider, including Plaintiff's, or patient would have used the device in the manner directed, had those facts been made known to the prescribing healthcare providers and/or the consumers of the device.

~~76.~~75. The warnings, labels, and instructions provided by the Defendants at all times relevant to this action, are and were inaccurate, intentionally misleading, and misinformed and misrepresented the risks and benefits and lack of safety and efficacy associated with the device.

~~77.~~76. The Defendants failed to perform, establish or otherwise facilitate adequate testing and/or quality assurance programs; either of which would have shown that the device posed serious and potential life threatening adverse effects and complications.

~~78.~~77. The health risks associated with the device as described herein are of such a nature that ordinary consumers would not have readily recognized the potential harm.

~~79.~~78. The device, which was designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold into the stream of commerce by the Defendants, was defective at the time of release into the stream of commerce due to inadequate warnings, labeling and/or instructions accompanying the product.

~~80.~~79. When Plaintiff-decedent was implanted with the device, the Defendants failed to provide any warnings, instructions, or labels regarding the severity and extent of health risks posed by the device, as discussed herein.

~~81.~~80. Neither Plaintiff-decedent nor her health care providers knew of the substantial danger associated with the intended and foreseeable use of the device as described herein until after Plaintiff's injury.

~~82.~~81. Plaintiff and her health care providers used the device in a normal, customary, intended, and foreseeable manner, namely as a surgically implanted device used to prevent pulmonary embolisms.

~~83.~~82. Upon information and belief, the defective and dangerous condition of the device, including the one implanted into Plaintiff, existed at the time they were manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold by the Defendants to distributors and/or healthcare professionals or organizations. Upon information and belief, the device implanted in Plaintiff was in the same condition

as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by the Defendants.

84.83. The Defendants' lack of sufficient warning and/or instructions was the direct and proximate cause of Plaintiff's serious physical injuries and economic damages in an amount to be determined at trial.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – DESIGN DEFECTS

(Against All Defendants)

85.84. Plaintiff-decedent re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

86.85. At all times relevant to this action, the Defendants developed, tested, designed, manufactured, inspected, labeled, promoted, distributed and sold into the stream of commerce the G2X Filter, including the one implanted in Plaintiff-decedent.

87.86. The G2X Filter was expected to, and did, reach its intended consumers without substantial change in the condition in which it was in when it left the Defendants' possession. In the alternative, any changes that were made to the G2X Filter implanted in Plaintiff were reasonably foreseeable to the Defendants.

88.87. The G2X Filter implanted in Plaintiff-decedent was defective in design because it failed to perform as safely as persons who ordinarily use the product would have expected at the time of use.

89.88. The G2X Filter implanted in Plaintiff-decedent was defective in design, in that its foreseeable risks of harm exceeded its claimed benefits.

~~90.~~89. Plaintiff-decedent used the G2X Filter in a manner that was reasonably foreseeable to the Defendants.

~~91.~~90. Neither Plaintiff-decedent, nor her health care providers could have by the exercise of reasonable care discovered the devices defective condition or perceived its unreasonable dangers prior to her implantation with the G2X Filter.

~~92.~~91. The G2X Filter's failure to perform safely and/or its defective design was the direct and proximate cause of Plaintiff's serious physical injuries and economic damages in an amount to be determined at trial.

FOURTH CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

(Against All Defendants)

~~93.~~92. Plaintiff-decedent re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

~~94.~~93. The Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the G2X Filter that was implanted into Plaintiff-decedent.

~~95.~~94. The G2X Filter implanted in Plaintiff-decedent contained a manufacturing defect when it left the Defendants' possession. The device differed from said Defendants' intended result and/or from other ostensibly identical units of the same product line.

~~96.~~95. Plaintiff-decedent and her health care providers used the G2X Filter in a way that was reasonably foreseeable to the Defendants.

~~97.~~96. The G2X Filter's manufacturing defect was the direct and proximate cause of Plaintiff's serious physical injuries and economic damages in an amount to be determined at trial.

FIFTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

(Against All Defendants)

~~98.~~97. Plaintiff-decedent re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

~~99.~~98. The Defendants through their officers, directors, agents, representatives, and written literature and packaging, and written and media advertisement, expressly warranted that the G2X Filter was safe and fit for use by consumers, was of merchantable quality, did not produce dangerous side effects, and was adequately tested and fit for its intended use.

~~100.~~99. At the time of making such express warranties, the Defendants knew and/or should have known that the G2X Filter did not conform to the express warranties and representations and that, in fact, the G2X Filter is not safe and poses serious health risks, of which the Defendants did not accurately warn.

~~101.~~100. As a foreseeable, direct, and proximate result of the breach of the express warranties, Plaintiff suffered severe personal injuries and economic loss.

~~102.~~101. Plaintiff-decedent, her health care providers, and other consumers relied on the express warranties made by the Defendants regarding the safety and efficacy of the G2X Filter and were reasonable in doing so.

~~103.~~102. The Defendants inclusive, and each of them, breached their express warranties because the G2X Filter was and continues to be defective and not reasonably safe for its intended purpose.

~~104.~~103. The Defendants expressly represented and warranted to the medical community and American consumers, including Plaintiff and her healthcare providers that the G2X Filter was safe and fit for the purposes intended, that it was of merchantable quality, that it did not pose dangerous health risks in excess of those risks associated with use of other similar devices, that the side effects it did produce were accurately reflected in the warnings, and that it was adequately tested and fit for its intended use.

~~105.~~104. The Defendants knew and should have known that the representations and express warranties were false, misleading, and untrue in that said Defendants knew the G2X Filter was not safe and fit for its intended use, and that the G2X Filter caused its users serious injuries that were not adequately warned of, identified, or represented by these Defendants.

~~106.~~105. As a foreseeable, direct and proximate result of the Defendants breaching their express warranties, as described herein, Plaintiff-decedent has suffered injuries as described herein.

SIXTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

(Against All Defendants)

~~107.~~106. Plaintiff-decedent re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

~~108.~~107. At all times relevant to this action, the Defendants designed, researched, developed, manufactured, tested, labeled, inspected, advertised, promoted, marketed, sold, and distributed into the stream of commerce the G2X Filter for use as a temporary surgically implanted device used to prevent pulmonary embolisms and for uses other than as approved and indicated in the product's instructions, warnings, and labels.

~~109.~~108. At the time and place of the sale, distribution, and supply of the defendants' G2X Filter to Plaintiff-decedent by way of her health care providers and medical facilities, the Defendants expressly represented and warranted, by labeling materials submitted with the product, that the G2X Filter was safe and effective for its intended use.

~~110.~~109. The Defendants knew of the intended use of the G2X Filter, at the time they marketed, sold, and distributed the product for use by Plaintiff, and impliedly warranted the product to be of merchantable quality, and safe and fit for its intended use.

~~111.~~110. The Defendants impliedly represented and warranted to the healthcare community, Plaintiff and her health care providers, that the G2X Filter was safe and of merchantable quality and fit for the ordinary purpose for which the product was intended and marketed to be used.

~~112.~~111. The representations and implied warranties made by the Defendants were false, misleading, and inaccurate because the G2X Filter was defective, unsafe, unreasonably dangerous, and not of merchantable quality, when used as it was marketed and intended to be used. Specifically, at the time Plaintiff-decedent purchased the G2X Filter from the Defendants, through her attending physicians and medical facilities, it was not in a merchantable condition in that:

a. It was designed in such a manner so as to be prone to a statistically high incidence of failure, including fracture, migration, excessive tilting, and perforation of the inferior vena cava;

b. It was designed in such a manner so as to result in a statistically significant incidence of injury to the organs and anatomy; and

c. It was manufactured in such a manner so that the exterior surface of the G2X Filter was inadequately, improperly and inappropriately prepared and/or finished causing the device to weaken and fail.

~~113.~~112. Plaintiff~~-decedent~~ and her health care providers reasonably relied on the superior skill and judgment of the Defendants as the designers, researchers and manufacturers of the product, as to whether G2X Filter was of merchantable quality and safe and fit for its intended use, and also relied on the implied warranty of merchantability and fitness for the particular use and purpose for which the G2X Filter was manufactured and sold.

~~114.~~113. The Defendants placed the G2X Filter into the stream of commerce in a defective, unsafe, and unreasonably dangerous condition, and the product was expected to and did reach Plaintiff without substantial change in the condition in which the G2X Filter was manufactured and sold.

~~115.~~114. The Defendants breached their implied warranty because their G2X Filter was not fit for its intended use and purpose.

~~116.~~115. As a proximate result of the Defendants breaching their implied warranties, Plaintiff was caused to suffer the injuries and damages described in this complaint.

SEVENTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

(Against All Defendants)

~~117.~~116. Plaintiff-decedent re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

~~118.~~117. At all times relevant to this cause, and as detailed *supra*, the Defendants negligently provided Plaintiff-decedent, the public at large, and the medical community, with false or incorrect information, or omitted or failed to disclose material information concerning the G2X Filter, including, but not limited to, misrepresentations relating to the following subject areas:

a. The safety of the G2X Filter;

b. The efficacy of the G2X Filter;

c. The rate of failure of the G2X Filter; and

d. The approved uses of the G2X Filter.

~~119.~~118. The information distributed by the Defendants to the public, the medical community and Plaintiff-decedent was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the G2X Filter. The Defendants made the foregoing misrepresentations knowing that they were false or without reasonable basis. These materials included instructions for use and warning document that was included in the package of the G2X Filter that was implanted in Plaintiff.

~~120.~~119. The Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff's healthcare providers; to gain the confidence of the public and the medical community, including Plaintiff-decedent's healthcare providers; to falsely assure them of the quality of the G2X Filter and its fitness for use; and to induce the public and the medical community, including Plaintiff-decedents's healthcare providers to request, recommend, prescribe, implant, purchase, and continue to use the G2X Filter.

~~121.~~120. The foregoing representations and omissions by the Defendants were in fact false. The G2X Filter is not safe, fit, and effective for human use in its intended and reasonably foreseeable manner. The use of the G2X Filter is hazardous to the user's health, and said device has a serious propensity to cause users to suffer serious injuries, including without limitation, the injuries Plaintiff-decedent suffered. Further, the device has a significantly higher rate of failure and injury than do other comparable devices.

~~122.~~121. In reliance upon the false and negligent misrepresentations and omissions made by the Defendants, Plaintiff-decedent and his health care providers were induced to, and did use the G2X Filter, thereby causing Plaintiff-decedent to sustain severe and permanent personal injuries. The Defendants knew and had reason to know that Plaintiff-decedent, her health care providers, and the general medical community did not have the ability to determine the true facts intentionally and/or negligently concealed and misrepresented by the Defendants, and would not have prescribed and implanted same, if the true facts regarding the device had not been concealed and misrepresented by the Defendants.

~~123.~~122. The Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who are implanted with the G2X Filter.

~~124.~~123. At the time the Defendants failed to disclose and misrepresented the foregoing facts, and at the time Plaintiff used the G2X Filter, Plaintiff and her health care providers were unaware of said Defendants' negligent misrepresentations and omissions.

~~125.~~124. Plaintiff-decedent, her health care providers and the general medical community reasonably relied upon the misrepresentations and omissions made by the Defendants where knowledge of the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of the G2X Filter.

125. Plaintiff-decedent and her health care provider's reliance on the foregoing misrepresentations and omissions by the Defendants was the direct and proximate cause of Plaintiff-decedent's harm as described herein.

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0 pt + Indent at: 18 pt

EIGHTEENTH CAUSE OF ACTION
SURVIVAL ACTION
(AGAINST ALL DEFENDANTS)

Formatted: No Spacing, Centered, Indent: Left: 0 pt, Line spacing: single

126. Plaintiff-decedent re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

Formatted: Expanded by 0.2 pt

127. As a direct and proximate result of the defendants' conduct, and failure to comply with applicable Federal Standards, as outlined above, Plaintiff-decedent suffered bodily injury and resulting pain and suffering, disability, disfigurement, mental anguish, loss of capacity of the enjoyment of life, expenses of hospitalization, medical and nursing care

Formatted: Font: Garamond, 12 pt

and treatment, and loss of earnings as well as loss of ability to earn money prior to Plaintiff-decedents death.

128. The representative of Plaintiff-decedent's estate bring this claim on behalf of Plaintiff-decedent's estate and Plaintiff-decedent's beneficiaries for damages.

129. The representatives/administrators of Plaintiff-decedent's estate further plead all survival damages allowed by statute and law in the state or states in which the causes of action accrued

Formatted: Add space between paragraphs of the same style, Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0 pt + Indent at: 18 pt, No widow/orphan control, Don't adjust space between Latin and Asian text, Don't adjust space between Asian text and numbers, Tab stops: 0 pt, Left

PUNITIVE DAMAGES ALLEGATIONS

(**Against All Defendants**)

~~126.~~130. Plaintiff-decedent re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

~~127.~~131. The Plaintiff-decedent is entitled to an award of punitive and exemplary damages based upon the Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and their complete and total reckless disregard for the public safety and welfare.

~~128.~~132. The Defendants had knowledge of and were in possession of evidence demonstrating that the G2X Filter was unreasonably dangerous and had a substantially higher failure rate than did other similar devices on the market. Yet, the Defendants failed to:

a. Inform or warn Plaintiff-decedent or her health care providers of the dangers;

b. To establish and maintain an adequate quality and post-market surveillance system; and

c. Recall the G2X Filter from the market.

~~129.~~133. The Defendants acted to serve their own interests and having reasons to know and consciously disregarding the substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others, and consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons.

~~130.~~134. As a direct, proximate, and legal result of the Defendants' acts and omissions a described herein, and Plaintiff's implantation with the G2X Filter, Plaintiff-decedent suffered serious injuries.

PRAYER FOR DAMAGES

WHEREFORE, ~~Plaintiff,~~ John Noterman, on behalf of the Estate of Pam W. Noterman, ~~PAMELA NOTERMAN~~, prays for relief on the entire complaint, as follows:

a. Awarding compensatory damages upon each cause of action;

b. Awarding actual damages to the Plaintiff-decedent Pam W. Noterman ~~PAMELA NOTERMAN~~ incidental to purchase and use of The G2X Filter System in an amount to be determined at trial;

c. Awarding punitive damages to the Plaintiff-decedents~~s~~;

d. Awarding pre-judgment and post-judgment interest to the Plaintiff-decedents~~s~~;

e. Awarding the costs and the expenses of this litigation to the Plaintiff~~s~~-decedents;

f. Awarding reasonable attorneys' fees and costs to the Plaintiff~~s~~decedents as provided by law; and

h. Granting all such other relief as the Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

John Noterman, as Representative of the Estate of Pam W. Noterman, ~~Plaintiff,~~ ~~PAMELA NOTERMAN,~~ demands a trial by jury on all triable issues in this civil action.

~~Dated this 13th day of February, 2015~~

~~Counsel for the Plaintiff~~

~~BY:~~
~~Jordan Chaikin, Esq.~~
~~*Daniel C. Burke, Esq.~~
~~Florida Bar No. 878421~~
~~Parker Waichman LLP~~
~~27300 Riverview Center Boulevard~~
~~Suite 103~~
~~Bonita Springs, Florida 34134~~
~~Phone: (239) 390-1000~~
~~Facsimile: (239) 390-0055~~

~~*Application for admission pro hac vice to be filed~~

Dated this 4th day of April, 2016

BY:/s/ *Matthew J. McCauley*
Matthew J. McCauley, Esq.
Parker Waichman LLP
6 Harbor Park Drive
Port Washington, NY 11050
Phone: (516) 466-6500
Facsimile: (516) 466-6665
E-mail: mmccauley@yourlawyer.com

Formatted: Superscript

Formatted: Indent: Left: 180 pt, First line: 36 pt

Formatted: Font: Italic